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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,247	11/05/1999	Thierry Sornasse	PA-0020 US	4960

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EXAMINER
SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
1631	13

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/435,247	Applicant(s) SORNASSE ET AL.	
	Examiner Monika B Sheinberg	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-9 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-9 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment A

Applicants' arguments, filed 28 February 2002 have been fully considered. The cancellation of claims 2-5 and 10-17 is acknowledged. Claims 1, 6-9 and 18-20 are pending.

The sequence restriction to SEQ ID NO:219 is hereby vacated and the pending claims have been examined in consideration of the collection of SEQ ID NO: 1-516.

Declaration

The declaration of Susan G. Stuart is acknowledged. The declaration is directed to the utility of the SEQ ID NO: 219 as per the 101 rejection in the office action mailed 1 October 2001. The claims are no longer directed to the specific SEQ ID NO: 219.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections are newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-9 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Claim 7 is directed to a method for detecting a polynucleotide in a sample using the composition of claim 1. Claim 8 is directed to a method of screening a library of molecules or compounds to identify a ligand using the composition of claim 1. The specification disclosure implies that such identified ligands and polynucleotides would provide information useful in diagnosis or treatment of disease. However, the fact that a hybridizing polynucleotide is present in a sample or a molecule that binds to the composition of claim 1 is identified does

not provide in and of itself any information useful to diagnosis or treatment. The composition of claims 1 is insufficiently characterized for diagnosis and treatment (see enablement rejection below). As such these methods would provide no useful information and therefore lack a specific, substantial, and credible utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-9 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The sequences disclosed by the applicant lack written description due to the number of sequences within SEQ ID NOs: 1-516 having unknowns or "unsure"s within the nucleic acid sequence. These wild cards do not disclose exactly that which was utilized by the applicant in order to accomplish the practice of the instant invention. The uncertainties create unknown sequences, each varying from the other by "a, t, c, g, or other" in many times more than just one location. For example, the following sequences list the uncertainties that vary from just a few locations to a range:

SEQ ID NO: 208 --*"unsure" 23, 29, 32, 62, 75, 97, 107, 110, 166, 210, 227, 230-231, 237-238, 243, 245-248, 251-253, 257, 260-262, 276-277, 283, 311, 317, 359, 434*

SEQ ID NO: 373 --*"unsure" 153, 177, 188, 224, 261, 276, 315, 346, 362*

SEQ ID NO: 438 --*"unsure" 17, 28, 30, 233-235*

SEQ ID NO: 478 --*"unsure" 138, 152, 158, 175, 185, 213, 223, 243, 258, 266, 288, 299, 306, 308, 316, 320-321, 328, 335-336, 343, 346, 371, 381, 392, 407, 420*

None of these additional sequences containing wild-cards or unsure positions meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the composition comprising SEQ ID NOs: 1-516 as claimed.

In addition, the libraries of "mimetics" and "peptide nucleic acids" in lines 1-2 of claim 9 lack written description. The mimetics encompassed by the claim are structurally unknown as to which compounds or molecules are mimicked; this is not disclosed by the specification. The peptide nucleic acids (PNA's), presumed artificial, are not structurally known either. The construction of PNA combines an unknown nucleic acid with a known or unknown peptide, leaving great uncertainty as to that which is being screened. Thus the SEQ ID NOs, the mimetic library, and the PNA library do not meet the written description provision of 35 USC 112, first paragraph.

Claims 1, 6 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPA 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The instant application fails to provide guidance to one of ordinary skill in the art for the method of screening a patient's sample for any immune response, disorder, condition, or disease as seen in claims 18-20 using the composition of claim 1. The example provided beginning on

page 26, discloses the sampling of peripheral blood mononuclear cells (PBMC) of two healthy individuals. The two samples were treated with different cocktails of cytokines in which the cytokines are at varied concentrations; for example, on page 26, the Group A cocktail includes pro-inflammatory cytokines such as these IL-6 at 10 ng/ml, IL-12 at 1 ng/ml, and IFNγ at 50 ng/ml. Due to the use of a mixture of cytokines it is unpredictable as to which particular cytokine had a specific effect on a specific regulation of a gene included by the collection of various SEQ ID NOs immobilized on a substrate. This demonstrates a significant degree of unpredictability in the art with respect to the binding of a cocktail of cytokines at varied concentrations to a plurality of potential cytokine regulated genes. It is also unpredictable as to which expression is representative of a particular immune disorder when the examples only represent TWO HEALTHY individuals. The simple listing of speculated associated disorders as seen on page 29 does not directly correlate to the experimental data of altered gene expression observed in SEQ ID NO: 1-516. The specification does not provide or suggest any correlation or linkage between the immune disorders or the SEQ ID NOs and the overall response of hybridization to the composition. One of ordinary skill in the art would not be able to extrapolate a prediction or diagnosis of any immune response, disorder, condition, or disease without undue experimentation and undefined further analyses of the experimental data to determine a potential correlation. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of descriptive working examples in the specification, and the unpredictability of diagnosis, the specification, as filed is not enabling for the method of screening for any immune response, disorder, condition, or disease. Note that the composition of claim 1 must be enabled for this use as this use is the only use set forth in the specification that is credible, specific, and substantial. There are no well known uses for the claimed composition and the other uses disclosed lack utility.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "specific" in claim 8 is a relative term which renders the claim indefinite. The term "specific" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification on page 7 lines 3-4 states that specific refers to a "specific interaction between two molecules" however an interaction between molecules has a very broad range of possibilities and interpretations. Thus the metes and bounds of that which defines "specific" are unclear. As such claim 9 is also indefinite due to its dependency from claim 8.

Claim 18 lack clarity in the claim language "immune response, disorder, condition or disease" lines 1-2. It is unclear if the applicant intended to screen the samples for all disorders, all conditions, and all diseases; or if the applicant intended to screen the samples for immune disorders, immune conditions, and immune diseases. As such claims 19 and 20 are also unclear due to their dependency from claim 18.

Claim 18 is indefinite for failing to recite a final process step which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. For example, claim 18 is drawn to a method for screening a patient's sample for "an immune response, disorder, condition, or disease" (lines 1-2), yet the claim recites a final lacking the immune response and including "immune disorder" instead of any disorder (as encompassed by the preamble). It is requested that the terms used be consistent. As such claims 19 and 20 are also unclear due to their dependency from claim 18.

The term "change" in claim 18 is a relative term which renders the claim indefinite. The term "change" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 20 is vague and indefinite due to the claim language "other atopic disorders" in lines 2-3. The metes and bounds of that which defines "other" are unclear.

Conclusion

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

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May 19, 2002

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MBS